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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,506	10/19/1999	SALVATORE ALBANI	246/285	4242

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/421,506	Albani
Examiner	**Art Unit**
G.R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 1, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *162-382* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *162-382* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's Amendment, Response and Election, filed 8/01/02, is acknowledged.

2. Applicant is advised that no determination as to the suitability of the drawings submitted in the application has yet been made.

3. Applicant's election of Group 15, Claims 220-228, in Paper No. 22, filed 8/01/02, with traverse, is acknowledged. Applicant indicates that a number of errors have been made in the restriction in that several groups have been improperly defined and certain claims have been placed in inappropriate groups. The Examiner appreciates Applicant's efforts in pointing out the errors. Given said errors in the previous restriction requirement, said requirement is hereby vacated. A new restriction follows. Previous Group 31 has been deleted. Claim 365 has been added to Group 50. Claim 368 has been added to Group 51. Previous Groups 1-3, Claims 162-167, have been properly restricted into new Groups 1-4. Applicant is advised that generic independent claims, such as 246-247, are included in several groups because of the recitation of the open term "comprising." The Examiner apologizes for any inconvenience or delay.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claim 162, drawn to a method of identifying T cells, classified in Class 435, subclass 7.1.

2. Claims 163, drawn to a method of isolating T cells, classified in Class 424, subclasses 278.1 and 534 and Class 435, subclass 7.1.

3. Claims 162, 164, and 166, drawn to a method of determining the quantity of T cells specific for an antigen of interest, classified in Class 424, subclasses 278.1 and 534 and Class 435, subclass 7.1.

4. Claims 162-167, drawn to a method of characterizing T cells, classified in Class 424, subclasses 278.1 and 534 and Class 435, subclass 7.1.

5. Claims 168-170, 173-175, 186-188, drawn to a method of modulating a T cell response from Th1 to Th2, classified in Class

424, subclasses 278.1 and 534.

6. Claims 168, 171-175, 189-194, drawn to a method of modulating a T cell response from Th2 to Th1, classified in Class 424, subclasses 278.1 and 534.

7. Claims 176-185, drawn to a method of characterizing T cells comprising isolating mRNA, classified in Class 435, subclass 6.

8. Claim 195, drawn to a method of identifying T cells specific for graft epitopes, classified in Class 435, subclass 7.1.

9. Claim 196, drawn to a method of treating a recipient, classified in Class 424, subclass 184.1.

10. Claims 197-214 and 381 drawn to a kit, classified in Class 435, subclass 810.

11. Claims 215 and 382, drawn to an immunomodulatory column, classified in Class 435, subclass 283.1.

12. Claims 216-217, drawn to a method of identifying a gene, classified in Class 435, subclass 6.

13. Claim 218, drawn to a method of obtaining a population of T cells, classified in Class 435, subclasses 7.1 and 325.

14. Claim 219, drawn to a method of monitoring an immunological outcome, classified in Class 435, subclass 7.1.

15. Claims 220-221, drawn to an artificial antigen presenting cell (aAPC) comprising a liposome, an MHC component, an antigen, an accessory molecule, and an orienting molecule, classified in Class 424, subclass 400 and Class 435, subclass 325.

16. Claims 220-228, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, and a surfactant, classified in Class 424, subclass 502 and Class 435, subclass 325.

17. Claims 229-231 and 246-247, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, and a co-stimulatory molecule, classified in Class 424, subclass 184.1 and Class 435, subclass 325.

18. Claims 229-231, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, and an adhesion molecule, classified in Class 424, subclass 461 and Class 435, subclass 325.

19. Claims 229-231 and 273-274, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, and a cell modulation molecule, classified in Class 424, subclass 418 and Class 435, subclass 325.

20. Claims 229-231, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, and an irrelevant molecule, classified in Class 424, subclass 400 and Class 435, subclass 325.

21. Claims 232-240 and 248-255, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, and a surfactant, classified in Class 424, subclass 502 and Class 435, subclass 325.

22. Claims 232-239 and 242, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, an adhesion molecule, and a surfactant, classified in Class 424, subclass 502 and Class 435, subclass 325.

23. Claims 232-239, 241, and 273-282, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a cell modulation molecule, and a surfactant, classified in Class 424, subclass 502 and Class 435, subclass 325.

24. Claims 232-239 and 243-245, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, an irrelevant molecule, and a surfactant, classified in Class 424, subclass 400 and Class 435, subclass 325.

25. Claims 246-247 and 256-258, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, and an adhesion molecule, classified in Class 424, subclass 461 and Class 435, subclass 325.

26. Claims 246-247, 256-258, and 300-301, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory

molecule, an orienting molecule, a co-stimulatory molecule, and a cell modulation molecule, classified in Class 424, subclass 418 and Class 435, subclass 325.

27. Claims 246-247 and 256-258, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, and an irrelevant molecule, classified in Class 424, subclasses 184.1 and 400 and Class 435, subclass 325.

28. Claims 246-247 and 256-259, 262-267, and 269, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, an adhesion molecule, and a surfactant, classified in Class 424, subclass 184.1 and Class 435, subclass 325.

29. Claims 246-247, 256-258, and 300-310, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, a cell modulation molecule, and a surfactant, classified in Class 424, subclass 184.1 and 502 and Class 435, subclass 325.

30. Claims 246-247, 256-258, 262-267, and 270-272, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, an irrelevant molecule, and a surfactant, classified in Class 435, subclass 325.

31. Claims 273-274 and 283-285, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a cell modulation molecule, and an adhesion molecule, classified in Class 424, subclass 418 and Class 435, subclass 325.

32. Claims 273-274 and 283-285, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a cell modulation molecule, and an irrelevant molecule, classified in Class 424, subclass 400 and Class 435, subclass 325.

33. Claims 273-293, and 295-296, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a cell modulation molecule, an adhesion molecule, and a surfactant, classified in Class 424, subclasses 418 and 502 and Class 435, subclass 325.

34. Claims 273-295, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a cell modulation molecule, a co-stimulatory molecule, and a surfactant, classified in Class 424, subclasses 184.1 and 502 and Class 435, subclass 325.

35. Claims 273-293, 295, and 297-299, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a cell modulation molecule, an irrelevant molecule, and a surfactant, classified in Class 424, subclasses 400 and 502 and Class 435, subclass 325.

36. Claims 300-301 and 311-313, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, a cell modulation molecule, and an adhesion molecule, classified in Class 424, subclasses 418 and 502 and Class 435, subclass 325.

37. Claims 300-301 and 311-313, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, a cell modulation molecule, and an irrelevant molecule, classified in Class 424, subclasses 400 and 502 and Class 435, subclass 325.

38. Claims 300-324, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, a cell modulation molecule, an adhesion molecule, and a surfactant, classified in Class 424, subclass 502 and Class 435, subclass 325.

39. Claims 300-323 and 325-327, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, a cell modulation molecule, an irrelevant molecule, and a surfactant, classified in Class 424, subclasses 400 and 418 and Class 435, subclass 325.

40. Claims 328-341, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a co-stimulatory molecule, a cell modulation molecule, an adhesion molecule, an irrelevant molecule, and a surfactant, classified in Class 424, subclass 400 and Class 435, subclass 325.

41. Claims 342-343, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, and a solid support, classified in Class 435, subclass 325.

42. Claims 342-350, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a solid support, and a surfactant, classified in Class 424, subclass 418 Class 435, subclass 325.

43. Claims 342-343 and 351-353, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a solid support, and a co-stimulatory molecule classified in Class 424, subclass 502 Class 435, subclass 325.

44. Claims 342-343 and 351-353, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a solid support, and an adhesion molecule classified in Class 424, subclass 461 Class 435, subclass 325.

45. Claims 342-343 and 351-353, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a solid support, and a cell modulation molecule classified in Class 424, subclass 416 Class 435, subclass 325.

46. Claims 342-343 and 351-353, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a solid support, an irrelevant molecule, classified in Class 424, subclass 400 Class 435, subclass 325.

47. Claims 342-362, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a solid support, a co-stimulatory molecule, and a surfactant, classified in Class 424, subclass 400 Class 435, subclass 325.

48. Claims 342-361 and 364, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a solid support, an adhesion molecule, and a surfactant, classified in Class 424, subclass 461 Class 435, subclass 325.

49. Claims 342-361 and 363, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a solid support, a cell modulation molecule, and a surfactant, classified in Class 424, subclass 416 Class 435, subclass 325.

50. Claims 342-361 and 365-367, drawn to an aAPC comprising a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a solid support, and an irrelevant molecule, and a surfactant, classified in Class 400, subclass 400 Class 435, subclass 325.

51. Claims 368-380, drawn to a method of making an aAPC, classified in Class 435, subclass 325.

4. Inventions 10-11, and 15-50 are different products. The Inventions comprise different combinations of the components: a liposome, an MHC component, an antigen, an accessory molecule, an orienting molecule, a solid support, a co-stimulatory molecule, a cell modulation molecule, an adhesion molecule, an irrelevant molecule, and a surfactant. As the different components of the aAPC confer different properties on the artificial cell, each particular combination will comprise a product with distinct properties. Therefore the Inventions are patentably distinct.

5. Inventions 51 and 15-50 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case the product as claimed can be made by adding the antigen after the incorporation of the MHC complex.

6. Inventions 10-11, and 15-50, and 1-9 and 12-14 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the products as claimed can be used in materially different processes, such as to produce antibodies.

7. Inventions 1-9, 12-14, and 51 are different methods. The methods employ different steps resulting in different end products or information. Note that certain methods, such as those of Groups 4 and 5, while grouped in the same classes, are mutually exclusive. Therefore the methods are patentably distinct

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Regardless of whichever Group Applicant should elect, Applicant is further required under 35 U.S.C. § 121 to elect:

A) a **specific** lipid,
B) a **specific** antigen,
C) a **specific** MHC component,
D) a **specific** accessory molecule,
E) a **specific** orienting molecule,
F) a **specific** co-stimulatory molecule, if one is desired,
G) a **specific** adhesion molecule, if one is desired,
H) a **specific** cell modulation molecule, if one is desired,
I) a **specific** irrelevant molecule, if one is desired,
I) a **specific** surfactant, if one is desired,

and list all Claims readable thereon including those subsequently added. Currently Claims 162-169, 171, 173-174, 176-185, 188, and 191-378 are generic.

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different lipids, antigens, MHC components, accessory molecules, orienting molecules, co-stimulatory molecules, adhesion molecules, cell modulation molecules, and irrelevant molecules, comprise different physiological properties, e.g., MHC class I's bind (and activate) different T cells than do MHC Class II's, and ICAMs bind different cells than do selectins. Therefore, the species are independent and patentable over one another.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is

(703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
October 17, 2002